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Yan Hong

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06/20/2005

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EXAMINER

MAHATAN, CHANNING

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,943

Applicant(s)

HONG ET AL.

Examiner

Channing S. Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

PROSECUTION IS REOPENED

Prosecution of this application is reopened to introduce new grounds of rejection as set forth below. For these reasons, the current action will be non-final.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) File a reply under 37 C.F.R. § 1.111 (if this Office action is non-final) or a reply under 37 C.F.R. § 1.113 (if this Office action is final); or,

(2) Request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 C.F.R. § 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 C.F.R. § 1.193(b)(2).

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-17.

Claims Rejected Under 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

NON-STATUTORY SUBJECT MATTER

The rejection of claim 17 under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter is maintained for reasons of record. The claimed invention is directed to a “computer readable medium having DNA fingerprint data record stored therein”.

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On page 13, lines 16-21 of the '*APPEAL BRIEF*', filed 15 November 2004, Applicants appear to be arguing that an interrelationship exists between the data stored in the medium and the process that is performed by the computer on such data because the instant claim 17 sets forth the data stored in the computer-readable storage medium is acted upon by a specific process executed by the computer thereby causing the data to be converted, wherein Applicants' state:

"Claim 17 is now in a form that provides a functional interrelationship between the descriptive material in the data record and a process of the computer that provides a practical application of the data record: namely, to produce a DNA fingerprint having practical application in the fields of genomics and biotechnology. As such, claim 17 now defines an article of manufacture (computer-readable storage medium) that has a practical application and that causes a computer to execute a specific process."

However, this is found unpersuasive and further clarification of this rejection is provided for below.

Applicants are directed to the following section of the M.P.E.P. for guidance of this rejection.

M.P.E.P. Section IV. DETERMINE WHETHER THE CLAIMED INVENTION COMPLIES WITH 35 U.S.C. 101, B. Classify the Claimed Invention as to Its Proper Statutory Category, 1. Nonstatutory Subject Matter, (b) Nonfunctional Descriptive Material states:

Descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition of matter and should be rejected under 35 U.S.C. 101. Thus, Office personnel should consider the claimed invention as a whole to determine whether the necessary functional interrelationship is provided. Where certain types of descriptive material, such as music, literature, art, photographs and mere arrangements or compilations of facts or data, are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer. Such "descriptive material" is not a process, machine, manufacture or composition of matter. (Data consists of facts, which become information when they are seen in context and convey meaning to people. Computers process data without any understanding of what that data represents. Computer Dictionary 210 (Microsoft Press, 2d ed. 1994).)

The policy that precludes the patenting of nonfunctional descriptive material would be easily frustrated if the same descriptive material could be patented when claimed as an article of manufacture. For example, music is commonly sold to consumers in the format of a compact disc. In such cases, the known compact disc acts as nothing more than a carrier for nonfunctional

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descriptive material. **The purely nonfunctional descriptive material cannot alone provide the practical application for the manufacture.** Office personnel should be prudent in applying the foregoing guidance. Nonfunctional descriptive material may be claimed in combination with other functional descriptive multi-media material on a computer-readable medium to provide the necessary functional and structural interrelationship to satisfy the requirements of 35 U.S.C. 101. The presence of the claimed nonfunctional descriptive material is not necessarily determinative of nonstatutory subject matter. For example, a computer that recognizes a particular grouping of musical notes read from memory and upon recognizing that particular sequence, causes another defined series of notes to be played, defines a functional interrelationship among that data and the computing processes performed when utilizing that data, and as such is statutory because it implements a statutory process.

M.P.E.P. section entitled "Statutory Process Claims" (page 2100-15, Column 1-2) states:

A claim that requires one or more acts to be performed defines a process. However, not all processes are statutory under 35 U.S.C. 101. Schrader, 22 F.3d at 296, 30 U.S.P.Q.2d at 1460. To be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan (discussed in i) below), or (B) be limited to a practical application within the technological arts (discussed in ii) below). See *Diamond v. Diehr*, 450 U.S. at 183-84, 209 U.S.P.Q. at 6 (quoting *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1877)) ("A [statutory] process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.... The process requires that certain things should be done with certain substances, and in a certain order; but the tools to be used in doing this may be of secondary consequence."). See also *Alappat*, 33 F.3d at 1543, 31 U.S.P.Q.2d at 1556-57 (quoting *Diamond v. Diehr*, 450 U.S. at 192, 209 U.S.P.Q. at 10). See also *id.* at 1569, 31 U.S.P.Q.2d at 1578-79 (Newman, J., concurring) ("unpatentability of the principle does not defeat patentability of its practical applications") (citing *O'Reilly v. Morse*, 56 U.S. (15 How.) at 114-19). If a physical transformation occurs outside the computer, a disclosure that permits a skilled artisan to practice the claimed invention, i.e., to put it to a practical use, is sufficient. On the other hand, it is necessary for the claimed invention taken as a whole to produce a practical application if there is only a transformation of signals or data inside a computer or if a process merely manipulates concepts or converts one set of numbers into another.

Again, the instant claim does not provide a functional interrelationship between the data record (non-functional descriptive material) and a process of the computer. The "DNA fingerprint data record" stored on the computer readable storage medium" in the instant claim can be reasonably interpreted to represent data (i.e. non-functional descriptive material) found on said "computer readable medium". An analogy for the instantly claimed invention would be that similar to music (i.e. data) on a compact disc (computer readable medium). Thus, "purely non-functional descriptive material cannot alone provide the practical application for the manufacture", and is thus non-statutory. The claims do not recite any concrete or tangible results; therefore the claims

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do not recite statutory subject matter. The computer-readable storage medium does not cause a computer to execute a specific process; absent is any executable code that would cause a computer to execute a specific process. Note the limitation "said computer converts said sequence of classified peak intensity symbols into a unique DNA fingerprint identifying a specific trait of said source of genomic DNA identified in said information field" appears to be directed to the computer rather than the computer readable medium, wherein no computer is actually claimed.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

LACK OF ENABLEMENT

Claims 1-17 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the

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prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Claims 1, 12, and all claims dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph. The claimed invention is directed to a method (instant claims 1-11) and computer program product (instant claims 12-16) "for obtaining DNA fingerprint profile data". The instant claims recites: 1) "...peak intensity...of each DNA fragment..."; and 2) the step "determining a sequence of fragments according to values of said bins", which appears to lack guidance, direction, or examples in the disclosure.

First, referring to the limitation "...peak intensity...of each DNA fragment..." the specification fails to enable a DNA fragment, per se, to have a peak intensity. While it is noted the specification on page 8, lines 1-30, does provide the following:

"A step 100, the labeled DNA fragments of a DNA sample that has been processed to obtain DNA markers according to any one of the abovementioned methods, are resolved, such as by running the sample through a gel electrophoresis. For example, using the AFLP technique, many small-sized PCR-generated fragments (typically in the range of 50-500 base pairs) are obtained, which comprises a DNA fingerprint. Depending upon whether radioisotope labeled primers or fluorescent labeled primers are used, different resolving processes are carried out. For radioisotope labeled primers, the samples are electrophoresed on a gel and the gel is exposed to X-ray film for several days. The exposed film is then manually interpreted. For fluorescent labeled primers, the samples are run on an electrophoresis gel and fluorescent emission signals are detected in real time by a fluorescent sensor (such as a CCD camera or the like). The signals are digitized and inputted into a host computer for processing. Results are provided in tabular form. The used of fluorescent labeled primers is thus much faster than radioisotopes primers and provides more reproducible results. An example, of an automatic sequencer suitable for use in obtaining DNA marker data is commercially available ABI 377 sequencer. Suitable DNA sequencers are available from a number of different manufacturers. At step 102, the peak intensities of each fragment and the size of the fragment (given in bps or base pair length) are measured (such as by the fluorescence sensor coupled to a host processor or computer)."

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It is reasonably interpreted from the above cited portion of the specification that peak intensity of a DNA fragment is measured in conjunction with either an appropriate fluorescent labeled primer or radioisotope labeled primer. However, the instant claims appear to limit the peak intensity of a DNA fragment to be solely from the DNA fragment. Thus, absent from the specification is guidance, direction, and working examples to provide that a DNA fragment has a peak intensity without a fluorescent labeled primer or radioisotope labeled primer.

Second, regarding the step for "determining a sequence of fragments according to values of said bins" the specification fails to provide procedures for said determination. The disclosure indicates that the "...present invention relates generally to DNA marker analysis and more particularly to methods for processing raw DNA marker profile data into a format that facilitates analysis of the raw data" (page 1, lines 4-7 and Figure 1). However, absent from the disclosure is any procedures and guidelines such that the values of bins determines the sequence of fragments (as instantly claimed) and in such absence one of skilled in the art would appear to be unable understand how to "determine a sequence of fragments according to the values of said bins." Further, undue experimentation would be required for the refinement and subsequent determination of procedures and parameters to be utilized for the value of bins to determine the sequence of fragment. Applicants are directed to *Fields, Wilkinson, and Kende v. Conover and Woodward* [170 USPQ 276; How-to-Make Requirement section] which states:

"the description must place the invention in the possession of the public as fully as if the art or instrument itself had been practically and publicly employed. In order to accomplish this, it must be so particular and definite that from it alone, without experiment or the exertion of his own inventive skill, any person versed in the art to which it appertains could construct and use it."

Such independent decisions, judgments, tests, and validation are not considered to be routine experimentation and one of skill in the art practicing the invention would be required to use

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inventive skill to develop protocols for the determination of the sequence of the fragments according to values of said bins.

Thus, the specification fails to provide one of skill in the art proper guidance, direction, or examples to enable the instantly claimed invention.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims 1-5, 9, 12, 16, 17, and all claims dependent therefrom utilize the abbreviations “DNA”, “AFLP”, “RFLP”, “SSCR PCR”, and “VNTR PCR”. Abbreviations in claims are considered vague and indefinite unless accompanied by the full name, usually in parentheses. Clarification of the metes and bounds, via clearer claim language, is requested.

MISSING ESSENTIAL STEP

Claims 1, 12, 17, and all claims dependent therefrom are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See M.P.E.P. § 2172.01. Instant claim 1 recites the step of “measuring peak intensity and size of each DNA fragment in a sample of genomic DNA”, however, absent to said “measurement of intensity and size of each DNA fragment” is the step of fragmenting the genomic DNA. Thus, the omitted step is: “fragmenting the genomic DNA”.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 17 is rejected under 35 U.S.C. § 102(b) as being anticipated by GeneScan® Reference Guide (GeneScan® Reference Guide: Chemistry Reference for the ABI Prism 310 Genetic Analyzer. The Perkin-Elmer Corporation. 1997, 246 pages).

GeneScan® Reference Guide discloses using the GeneScan® Analysis Software to analyze data collected by the ABI Prism 310 Genetic Analyzer to size and quantitate DNA fragments, wherein the establishment of a baseline, adjustment for spectral overlap of the dyes, peak detection, and size calling are also provided for (page 2-1 ‘*Introduction*’ section; page). GeneScan® Reference Guide indicates the intensity of emitted fluorescence is different among the various applied fluorescent dyes and allows for classification of the peak intensities based on these levels (page 2-3, lines 16-28; and 4-3 to 4-4 ‘*Understanding Dye Spectra*’). The reference describes the “binning” (grouping) of allele fragments based upon size to obtain allele definition (page 8-12 ‘*Analyzing Data, Part II – Allele Binning Using Genotyper 2.0*’). Information pertaining to run information, data collection settings, gel information, sample information (i.e. source, method of producing, etc.), and analysis records (spacing, start/end size, etc.) are recorded (i.e. stored on computer readable medium) (instant claim 17; page 3-7, lines 5-22). The reference provides utilizing the disclosed analysis software in the detection of samples obtained by AFLP to derive fingerprints allowing individuals to be genotyped or differentiated based on

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the alleles they carry (pages 10-1 to 10-4; and Figure 10-4). Thus, GeneScan® Reference Guide anticipates the instantly claimed invention.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The Fax Center number is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify Applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables Applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Examiner Initials: *CSM*Date: *June 13, 2005*

Ardin H. Marschel 6/13/05
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER